

AMENDED IN ASSEMBLY AUGUST 27, 2007

AMENDED IN ASSEMBLY JULY 17, 2007

AMENDED IN SENATE MAY 16, 2007

AMENDED IN SENATE APRIL 9, 2007

**SENATE BILL**

**No. 164**

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**Introduced by Senator Migden**

January 31, 2007

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An act to amend Sections 124977 and 125002 of the Health and Safety Code, relating to maternal and child health, ~~and making an appropriation therefor.~~

LEGISLATIVE COUNSEL'S DIGEST

SB 164, as amended, Migden. Prenatal screening.

Existing law imposes various responsibilities upon the State Department of Public Health and prenatal care providers with respect to prenatal care, screening, and counseling, and requires the department to administer a statewide program for prenatal testing for genetic disorders and birth defects, including, but not limited to, ultrasound, amniocentesis, chorionic villus sampling, and blood testing for genetic disorders and birth defects. Existing law establishes the Birth Defects Monitoring Program in the department's Maternal, Child, and Adolescent Health program, and requires the Deputy Director for Maternal, Child, and Adolescent Health to maintain a system for the collection of prescribed information on birth defects. Existing law also provides for an increase in prenatal screening fees to support the program activities and specifies the steps for release of pregnancy blood samples for research purposes. Existing law requires that those fees be deposited in the continuously appropriated Genetic Testing Fund.

This bill would change the name of the Birth Defects Monitoring Program to the Birth Defects Monitoring and Biomedical Resources Program. The bill would require the department to also charge investigators, who are approved by the department to use pregnancy blood for research purposes, a fee for costs related to data linkage, storage, retrieval, processing, data entry, reinventory, and shipping of pregnancy blood or its components, and related data management, as provided. The bill would require that the moneys collected from the prenatal fee increase and the usage and retrieval charge be deposited in the Birth Defects Monitoring and Biomedical Resources Program Fund, which the bill would create, ~~and that would be continuously appropriated~~ to support the activities of the program, *upon appropriation by the Legislature*. The bill would also specify that, in addition to the fee imposed pursuant to those provisions, a for-profit investigator approved by the department shall be required to enter into a written contract or agreement that requires, as a condition of accepting the sample, the payment to the department of a specified percentage of net revenues, received by the investigator that are based, in whole or in part, on samples the investigator received from the program, as provided. The bill would require the department to deposit any moneys received from a for-profit investigator pursuant to those provisions into the Birth Defects Monitoring and Biomedical Resources Program Investigation Account in the fund, which the bill would create, and would require that those moneys be available for expenditure by the department, upon appropriation by the Legislature, for purposes of implementing and administering of the program.

The bill would additionally require that the program develop pregnancy blood collection and processing protocols, determine conditions and recommendations for the duration of pregnancy blood storage, establish exclusion criteria for blood specimens, and institute safe and secure methods for the disposal of specimens, as determined by the program. The bill would require the department to store the pregnancy blood for research purposes, as prescribed, and analyze the costs of pregnancy blood storage, and annual data linkage and management, and to adjust the fee accordingly.

Existing law prohibits the release of information identifying the person whose pregnancy blood samples are stored, analyzed, or otherwise shared for research purposes with nondepartment staff.

This bill would exempt from that prohibition the provision of information identifying the person from whom the samples were

obtained to Birth Defects Monitoring and Biomedical Resources Program contractors or other entities approved by the department.

The Committee for the Protection of Human Subjects (CPHS) serves as the institutional review board for the California Health and Human Services Agency for the purpose of assuring that research involving human subjects is conducted ethically and with minimum risk to participants.

This bill would require CPHS to determine if certain criteria are met to ensure the confidentiality of a donor's personal information before pregnancy blood is released for research purposes, as provided.

The bill would also authorize the department to bill investigators who are approved by the department to use pregnancy blood for research purposes for reasonable costs associated with the department's process of protecting personal information, including, but not limited to, the department's costs for conducting a portion of the data processing for the investigator, removing personal information, encrypting or otherwise securing personal information, or assigning subject codes. The bill would also require the department, health care providers, and local health departments to maintain the confidentiality of patient information in the same manner as other medical record information with patient identification as required by existing law, and would require this information to be used only for prescribed purposes.

Vote: majority. Appropriation: ~~yes~~*no*. Fiscal committee: yes. State-mandated local program: no.

*The people of the State of California do enact as follows:*

1     SECTION 1. Section 124977 of the Health and Safety Code  
2     is amended to read:  
3     124977. (a) It is the intent of the Legislature that, unless  
4     otherwise specified, the program carried out pursuant to this chapter  
5     be fully supported from fees collected for services provided by the  
6     program.  
7     (b) (1) The department shall charge a fee to all payers for any  
8     tests or activities performed pursuant to this chapter. The amount  
9     of the fee shall be established by regulation and periodically  
10    adjusted by the director in order to meet the costs of this chapter.  
11    Notwithstanding any other provision of law, any fees charged for  
12    prenatal screening and followup services provided to persons  
13    enrolled in the Medi-Cal program, health care service plan

1 enrollees, or persons covered by health insurance policies, shall  
2 be paid in full directly to the Genetic Disease Testing Fund, subject  
3 to all terms and conditions of each enrollee's or insured's health  
4 care service plan or insurance coverage, whichever is applicable,  
5 including, but not limited to, copayments and deductibles  
6 applicable to these services, and only if these copayments,  
7 deductibles, or limitations are disclosed to the subscriber or enrollee  
8 pursuant to the disclosure provisions of Section 1363.

9 (2) The department shall expeditiously undertake all steps  
10 necessary to implement the fee collection process, including  
11 personnel, contracts, and data processing, so as to initiate the fee  
12 collection process at the earliest opportunity.

13 (3) The director shall convene, in the most cost-efficient manner  
14 and using existing resources, a working group comprised of health  
15 insurance, health care service plan, hospital, consumer, and  
16 department representatives to evaluate newborn and prenatal  
17 screening fee billing procedures, and recommend to the department  
18 ways to improve these procedures in order to improve efficiencies  
19 and enhance revenue collections for the department and hospitals.  
20 In performing its duties, the working group may consider models  
21 in other states. The working group shall make its recommendations  
22 by March 1, 2005.

23 (4) Effective for services provided on and after July 1, 2002,  
24 the department shall charge a fee to the hospital of birth, or, for  
25 births not occurring in a hospital, to families of the newborn, for  
26 newborn screening and followup services. The hospital of birth  
27 and families of newborns born outside the hospital shall make  
28 payment in full to the Genetic Disease Testing Fund. The  
29 department shall not charge or bill Medi-Cal beneficiaries for  
30 services provided under this chapter.

31 (5) (A) The department shall charge an additional fee for  
32 prenatal screening to support the pregnancy blood sample storage,  
33 testing, and research activities of the Birth Defects Monitoring and  
34 Biomedical Resources Program activities.

35 (B) The prenatal screening fee increase for activities of the Birth  
36 Defects Monitoring and Biomedical Resources Program shall be  
37 ten dollars (\$10).

38 (C) The department shall also charge investigators who are  
39 approved by the department a fee for costs related to data linkage,  
40 storage, retrieval, processing, data entry, reinventory, and shipping

1 of pregnancy blood or its components and related data  
2 management. The funds from fees collected pursuant to this  
3 subparagraph may be charged and collected by the department or  
4 by an entity authorized by the department to meet those costs.

5 (D) (i) In addition to the fee imposed pursuant to this paragraph,  
6 a for-profit investigator approved by the department shall be  
7 required to enter into a written agreement or contract that requires,  
8 as a condition of accepting the sample, that the investigator pay  
9 the following amounts to the department:

10 (I) Five percent of any net revenues in excess of two hundred  
11 fifty thousand dollars (\$250,000) received by that investigator  
12 based, in whole or in part, on samples the investigator received  
13 from the Birth Defects Monitoring and Biomedical Resources  
14 Program.

15 (II) Twenty-five percent of any net licensing revenues in excess  
16 of two hundred fifty thousand dollars (\$250,000) received by the  
17 for-profit investigator that are associated with any drug or product  
18 that is developed and based, in whole or in part, on samples the  
19 investigator received from the Birth Defects Monitoring and  
20 Biomedical Resources Program.

21 (ii) The department shall deposit any moneys received from a  
22 for-profit investigator pursuant to clause (i) into the Birth Defects  
23 Monitoring and Biomedical Resources Program Investigation  
24 Account, which is hereby created in the Birth Defects Monitoring  
25 and Biomedical Resources Program Fund. Moneys in that account,  
26 including, notwithstanding Section 16305.7 of the Government  
27 Code, interest and dividends earned on moneys in the account shall  
28 be available for expenditure by the department, upon appropriation  
29 by the Legislature, for purposes of implementing and administering  
30 the program.

31 (E) The funds from fees collected pursuant to this paragraph  
32 shall be deposited into the Birth Defects Monitoring and  
33 Biomedical Resources Program Fund, which is hereby created as  
34 a special fund in the State Treasury, to be ~~continuously~~  
35 ~~appropriated~~ *used by the department, upon appropriation by the*  
36 *Legislature*, to carry out the purposes of the Birth Defects  
37 Monitoring and Biomedical Resources Program. Notwithstanding  
38 Section 16305.7 of the Government Code, interest earned on the  
39 moneys in the fund shall also be deposited as revenue into the fund  
40 to support the program.

(c) (1) The Legislature finds that timely implementation of changes in genetic screening programs and continuous maintenance of quality statewide services requires expeditious regulatory and administrative procedures to obtain the most cost-effective electronic data processing, hardware, software services, testing equipment, and testing and followup services.

(2) The expenditure of funds from the Genetic Disease Testing Fund and the Birth Defects Monitoring and Biomedical Resources Program Fund for purposes related to prenatal and newborn screening and for the expansion of the Genetic Disease Branch Screening Information System, including necessary data linkages, as determined by the department, shall not be subject to any of the following:

(A) Division 25.2 (commencing with Section 38070), Chapter 2 (commencing with Section 10290), or Chapter 3 (commencing with Section 12100) of Part 2 of Division 2 of the Public Contract Code.

(B) Article 4 (commencing with Section 19130) of Chapter 5 of Part 2 of Division 5 of Title 2 of the Government Code.

(C) Sections 4800 to 5180, inclusive, of the State Administrative Manual, as those sections relate to approval of information technology projects or approval of increases in the duration or costs of information technology projects.

(D) Provision 4 of Item 4265-001-0001 of Section 2.00 of the Budget Act of 2007, and related Budget Act provisions. The department shall provide the Department of Finance with documentation that equipment and services have been obtained at the lowest cost consistent with technical requirements for a comprehensive, high-quality program. This paragraph shall apply to the design, development, and implementation of any expansion, and to the maintenance and operation of, the Genetic Disease Branch Screening Information System, including change requests, once the expansion is implemented.

(3) The expenditure of funds from the Genetic Disease Testing Fund for implementation of the Tandem Mass Spectrometry screening for fatty acid oxidation, amino acid, and organic acid disorders, and screening for congenital adrenal hyperplasia may be implemented through the amendment of the Genetic Disease Branch Screening Information System contracts and shall not be subject to Chapter 3 (commencing with Section 12100) of Part 2

1 of Division 2 of the Public Contract Code, Article 4 (commencing  
2 with Section 19130) of Chapter 5 of Part 2 of Division 5 of Title  
3 2 of the Government Code, and any policies, procedures,  
4 regulations or manuals authorized by those laws.

5 (4) The expenditure of funds from the Genetic Disease Testing  
6 Fund for the expansion of the Genetic Disease Branch Screening  
7 Information System to include cystic fibrosis and biotinidase may  
8 be implemented through the amendment of the Genetic Disease  
9 Branch Screening Information System contracts, and shall not be  
10 subject to Chapter 2 (commencing with Section 10290) or Chapter  
11 3 (commencing with Section 12100) of Part 2 of Division 2 of the  
12 Public Contract Code, Article 4 (commencing with Section 19130)  
13 of Chapter 5 of Part 2 of Division 5 of Title 2 of the Government  
14 Code, or Sections 4800 to 5180, inclusive, of the State  
15 Administrative Manual as they relate to approval of information  
16 technology projects or approval of increases in the duration or  
17 costs of information technology projects. This paragraph shall  
18 apply to the design, development, and implementation of the  
19 expansion, and to the maintenance and operation of the Genetic  
20 Disease Branch Screening Information System, including change  
21 requests, once the expansion is implemented.

22 (d) (1) The department may adopt emergency regulations to  
23 implement and make specific this chapter in accordance with  
24 Chapter 3.5 (commencing with Section 11340) of Part 1 of Division  
25 3 of Title 2 of the Government Code. For the purposes of the  
26 Administrative Procedure Act, the adoption of regulations shall  
27 be deemed an emergency and necessary for the immediate  
28 preservation of the public peace, health and safety, or general  
29 welfare. Notwithstanding Chapter 3.5 (commencing with Section  
30 11340) of Part 1 of Division 3 of Title 2 of the Government Code,  
31 these emergency regulations shall not be subject to the review and  
32 approval of the Office of Administrative Law. Notwithstanding  
33 Sections 11346.1 and 11349.6 of the Government Code, the  
34 department shall submit these regulations directly to the Secretary  
35 of State for filing. The regulations shall become effective  
36 immediately upon filing by the Secretary of State. Regulations  
37 shall be subject to public hearing within 120 days of filing with  
38 the Secretary of State and shall comply with Sections 11346.8 and  
39 11346.9 of the Government Code or shall be repealed.

(2) The Office of Administrative Law shall provide for the printing and publication of these regulations in the California Code of Regulations. Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the regulations adopted pursuant to this chapter shall not be repealed by the Office of Administrative Law and shall remain in effect until revised or repealed by the department.

(3) The Legislature finds and declares that the health and safety of California newborns is in part dependent on an effective and adequately staffed genetic disease program, the cost of which shall be supported by the fees generated by the program.

SEC. 2. Section 125002 of the Health and Safety Code is amended to read:

125002. (a) In order to align closely related programs and in order to facilitate research into the causes of, and treatment for, birth defects, the Birth Defects Monitoring and Biomedical Resources Program provided for pursuant to Chapter 1 (commencing with Section 103825) of Part 2 of Division 102 shall become part of the Maternal, Child, and Adolescent Health program provided for in Article 1 (commencing with Section 123225) of Chapter 1 of Part 2 of Division 106.

(b) The Birth Defects Monitoring and Biomedical Resources Program shall develop blood collection and processing protocols, determine conditions and duration of pregnancy blood storage, establish exclusion criteria for pregnancy blood specimens, and institute safe and secure methods of disposing of specimens, as determined by the program. In addition, the Birth Defects Monitoring and Biomedical Resources Program or another entity authorized by the department shall store the pregnancy blood for research purposes from all or a statistically representative sample population of pregnant women who provided a positive consent.

(c) The department shall analyze the costs of pregnancy blood storage and data linkage and management annually, and the amount of the fee shall be adjusted by the department to meet the costs of the Birth Defects Monitoring and Biomedical Resources Program activities.

(d) It is the intent of the Legislature that pregnancy blood samples, taken for prenatal screening, shall be stored and used only for the following purposes:



1 (1) Research to identify risk factors for children's and women's  
2 diseases.

3 (2) Research to develop and evaluate screening tests.

4 (3) Research to develop and evaluate prevention strategies.

5 (4) Research to develop and evaluate treatments.

6 (e) Before any pregnancy blood samples are released for  
7 research purposes, all of the following conditions must be met:

8 (1) Individual consent at the time the sample is drawn to allow  
9 confidential use of the sample for research purposes by the  
10 department or the department's approved researchers.

11 (2) Protocol review for scientific merit by the department or  
12 another entity authorized by the department.

13 (3) Protocol review by the State Committee for the Protection  
14 of Human Subjects (CPHS), as described in subdivision (i).

15 (f) When pregnancy blood samples are stored, analyzed, or  
16 otherwise shared for research purposes with nondepartment staff,  
17 no information may be released identifying the person from whom  
18 the samples were obtained, except that information may be  
19 provided to Birth Defects Monitoring and Biomedical Resources  
20 Program contractors or to other entities approved by the  
21 department. Contractors and other entities approved by the  
22 department pursuant to this subdivision shall comply with the  
23 confidentiality requirements regarding patient information  
24 prescribed in subdivision (h).

25 (g) Since the pregnancy blood samples described in this section  
26 will be stored by the Birth Defects Monitoring and Biomedical  
27 Resources Program or another entity authorized by the State  
28 Department of Health Services, Section 103850, pertaining to  
29 confidentiality of information, is applicable.

30 (h) The department, health care providers, and local health  
31 departments shall maintain the confidentiality of patient  
32 information in accordance with existing law and in the same  
33 manner as other medical record information with patient  
34 identification that they possess, and shall use the information only  
35 for the following purposes:

36 (1) Research to identify risk factors for children's and women's  
37 diseases.

38 (2) Research to develop and evaluate screening tests.

39 (3) Research to develop and evaluate prevention strategies.

40 (4) Research to develop and evaluate treatments.

(i) (1) In conducting the protocol review required by paragraph (3) of subdivision (e), CPHS shall determine if all of the following criteria have been met:

(A) The Birth Defects Monitoring and Biomedical Resources Program contractors or other entities approved by the department have provided a plan sufficient to protect personal information from improper use and disclosures, including sufficient administrative, physical, and technical safeguards to protect personal information from reasonable anticipated threats to the security or confidentiality of the information.

(B) The Birth Defects Monitoring and Biomedical Resources Program contractors or other entities approved by the department have provided a sufficient plan to destroy or return all personal information as soon as it is no longer needed for the research activity, unless the program contractors or other entities approved by the department have demonstrated an ongoing need for the personal information for the research activity and have provided a long-term plan sufficient to protect the confidentiality of that information.

(C) The Birth Defects Monitoring and Biomedical Resources Program contractors or other entities approved by the department have provided sufficient written assurances that the personal information will not be reused or disclosed to any other person or entity, or used in any manner not approved in the research protocol, except as required by law or for authorized oversight of the research activity.

(2) As part of its review and approval of the research activity for the purpose of protecting personal information held in agency databases, CPHS shall accomplish at least all of the following:

(A) Determine whether the requested personal information is needed to conduct the research.

(B) Permit access to personal information only if it is needed for the research activity.

(C) Permit access only to the minimum necessary personal information needed for the research activity.

(D) Require the assignment of unique subject codes that are not derived from personal information in lieu of social security numbers if the research can still be conducted without social security numbers.

1 (E) If feasible, and if cost, time, and technical expertise permit,  
2 require the agency to conduct a portion of the data processing for  
3 the researcher to minimize the release of personal information.

4 (j) In addition to the fee described in subparagraph (C) of  
5 paragraph (5) of subdivision (b), the department may bill an  
6 investigator for the costs associated with the department's process  
7 of protecting personal information, including, but not limited to,  
8 the department's costs for conducting a portion of the data  
9 processing for the investigator, removing personal information,  
10 encrypting or otherwise securing personal information, or assigning  
11 subject codes.

12 (k) Nothing in this section shall prohibit the department from  
13 using its existing authority to enter into written agreements to  
14 enable other institutional review boards to approve research  
15 activities, projects or classes of projects for the department,  
16 provided the data security requirements set forth in this section  
17 are satisfied.